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UNITED STATES DEPARTMENT OF COMMERCE  
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Washington, D.C. 20231

#41

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,639,436 was filed on February 11, 1997, under 35 U.S.C. § 156. U.S. Patent No. 4,639,436 issued on January 27, 1987 from an application that was filed on August 23, 1978. Accordingly, the original expiration date of the patent is January 27, 2004. 35 U.S.C. § 154. A copy of a supplement filed February 12, 1997 is also attached.

The assistance of your Office is requested in confirming that the product identified in the application, GLYSET (Mitigol), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.

A handwritten signature in cursive script, appearing to read "Karin Tyson", written over a horizontal line.

Karin Tyson  
Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Project

cc: Jeffrey M. Greenman, Esq.  
Bayer Corporation  
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West Haven, CT 06516